

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER)	
INTELLECTUAL PROPERTY GMBH and)	
BAYER HEALTHCARE)	
PHARMACEUTICALS INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 12-517 (GMS)
v.)	CONSOLIDATED
)	
WATSON LABORATORIES INC., et al.)	
)	
Defendants.)	

PLAINTIFFS' MOTION FOR AN AMENDED JUDGMENT

Pursuant to Fed. R. Civ. P. 59, Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals, Inc. (collectively “Plaintiffs” or “Bayer”) respectfully move for the entry of the attached Amended Final Judgment Order, which recites the relief contemplated by the Hatch-Waxman Act where, as here, the brand company has prevailed. Pursuant to D. Del. LR 7.1.1, Bayer sought Defendants’ consent to this motion, but they did not respond to Bayer’s inquiries.

By Memoranda issued on April 27, 2016 (D.I. 172) and May 2, 2016 (D.I. 175), and its ruling stated on the record at the close of trial, Tr. 1170-76, the Court has ruled that Watson’s ANDA product infringes the asserted claims of U.S. Patent No. 6,362,178 (“the ’178 patent”), U.S. Patent No. 7,696,206 (“the ’206 patent”), and U.S. Patent No. 8,613,950 (“the ’950 patent”) and that those claims are not invalid. On May 2, 2016, the Court entered judgment in the above-captioned case in favor of Bayer and against Watson. D.I. 177. The Court’s judgment, however, did not order any particular relief, such as ordering the effective date of approval of Watson’s ANDA.

Section 271(e)(4)(A) of Title 35 provides that, upon finding in favor of the patentee in an ANDA case such as this, “the court shall order the effective date of any approval of the drug ... involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.”

Bayer’s Complaint and post-trial briefing requested that the Court order that the effective date of an FDA approval of Watson’s ANDA No. 203689 be not earlier than the latest of the expiration of the ’178 patent (October 31, 2018), the ’206 patent (October 31, 2018), and the ’950 patent (December 23, 2028), as well as any applicable exclusivities and extensions. *See* D.I. 1 (C.A. 12-517) at 11; D.I. 1 (C.A. 14-760) at 9; D.I. 147 (C.A. 12-517) at Ex. A; D.I. 148 (C.A. 12-517) at Ex. A. In its post-trial submission, Watson never disputed or contested that this relief should be awarded to Bayer if the patents were determined to be valid and infringed.

Accordingly, Bayer respectfully requests that the Court amend the Final Judgment entered in this matter and enter the attached proposed Amended Final Judgment Order (Exhibit A), which recites the terms of the parties’ previous stipulations of infringement and provides, *inter alia*, as follows:

1. The drug product that is the subject of Defendant Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc.’s (“Watson”) Abbreviated New Drug Application (“ANDA”) No. 203689 (including any amendments or supplements thereto) (“Watson’s ANDA Product”), as well as the active ingredient therein, infringe each of claims 1-5 of the ’178 patent and claims 1-3 of the ’206 patent. Watson’s ANDA Product also infringes each of claim 7 of the ’178 patent, claim 4 of the ’206 patent, and claims 9 and 11 of the ’950 patent. In addition, the use of Watson’s ANDA Product, as well as the use of the active ingredient contained therein, in

accordance with the label submitted in Watson's ANDA No. 203689, infringe each of claim 8 of the '178 patent and claims 5-6 of the '206 patent.

2. Claims 1-5, 7, and 8 of the '178 patent are not invalid due to obviousness.

3. Claims 1-6 of the '206 patent are not invalid due to obviousness.

4. Claims 9 and 11 of the '950 patent are not invalid due to obviousness or for indefiniteness.

5. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any Food and Drug Administration approval of Watson's ANDA No. 203689 shall be a date not earlier than the latest of the expiration of the '178 patent (October 31, 2018), the '206 patent (October 31, 2018), and the '950 patent (December 23, 2028), as well as any applicable exclusivities and extensions.

6. Judgment is hereby entered in favor of Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. (collectively "Bayer") and against Watson on (a) Bayer's claim of infringement of claims 1-5, 7, and 8 of the '178 patent; (b) Bayer's claim of infringement of claims 1-6 of the '206 patent; (c) Bayer's claim of infringement of claims 9 and 11 of the '950 patent; and (d) Watson's counterclaims seeking declaratory judgments of non-infringement and invalidity with respect to the '178, '206, and '950 patents.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

OF COUNSEL:

Bruce R. Genderson
Adam L. Perlman
Aaron P. Maurer
David I. Berl
Dov P. Grossman
Thomas S. Fletcher
Galina I. Fomenkova
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
(202) 434-5000

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com

*Attorneys for Plaintiffs Bayer Pharma AG,
Bayer Intellectual Property GmbH and
Bayer HealthCare Pharmaceuticals Inc.*

May 11, 2016

RULE 7.1.1 CERTIFICATE

I hereby certify that Bayer's counsel sought Defendants' consent to this motion,
but Defendants' counsel did not respond to Bayer's inquiries.

/s/ Rodger D. Smith II

Rodger D. Smith II (#3778)

CERTIFICATE OF SERVICE

I hereby certify that on May 11, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 11, 2016, upon the following in the manner indicated:

John C. Phillips, Jr., Esquire
Megan C. Haney, Esquire
David A. Bilson, Esquire
PHILLIPS, GOLDMAN & SPENCE, P.A.
1200 North Broom Street
Wilmington, DE 19806
Attorneys for Defendants
Watson Laboratories Inc.,
Actavis, Inc. and Actavis Pharma, Inc.

VIA ELECTRONIC MAIL

J. Coy Stull, Esquire
William G. James, Esquire
GOODWIN PROCTER LLP
901 New York Avenue, NW
Washington, DC 20001
Attorneys for Defendants
Watson Laboratories Inc.,
Actavis, Inc. and Actavis Pharma, Inc.

VIA ELECTRONIC MAIL

Robert V. Cerwinski, Esquire
Elizabeth J. Holland, Esquire
Brian J. Robinson, Esquire
Andrew E. Riley, Esquire
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Attorneys for Defendants
Watson Laboratories Inc.,
Actavis, Inc. and Actavis Pharma, Inc.

VIA ELECTRONIC MAIL

J. Anthony Downs, Esquire
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
*Attorneys for Defendants
Watson Laboratories Inc.,
Actavis, Inc. and Actavis Pharma, Inc.*

VIA ELECTRONIC MAIL

/s/ Rodger D. Smith II

Rodger D. Smith II (#3778)